REMARKS

Claims 11, 13-15 and 30-34 are currently pending. In the Office Action mailed June 28, 2005, the Examiner has raised the following issues, which are set forth below by number in the order they are addressed herein:

1) Claims 11 and 30-34 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;

2) Claim 30 stands rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Hillier *et al.*, GENBANK Accession No. AA402683 (1997).

Applicants thank the Examiner for indicating that Claims 13-15 are allowed. Even so, Applicants hereby amend Claim 30 in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s). This amendment does not introduce new matter and does not narrow the scope of any of the claims within the meaning of *Festo*.[1]

1) The Claims Meet The Written Description Requirement

The Examiner has rejected Claims 11 and 30-34 under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement for containing subject matter which was not described in the Specification in a way as to convey that the inventors had possession of the claimed invention. Regarding Claims 11 and 31-34, the Examiner states:

> [n]ucleic acids that encode peptides having at least 90% amino acid identity to SEQ ID NO: 2 constitute a large genus of compounds and include sequences where the region of non-identity is interspersed throughout the sequence in either a regular or random fashion. The polypeptide resulting from this situation would have amino acid sequences quite different from that of SEQ ID NO: 2 with no guarantee of similar function to that of SEQ ID NO: 2 (Final Office Action, pages 4 and 5).

Applicants respectfully disagree that the claims fail to meet the written description requirement and that the skilled artisan could not readily ascertain the structures of the claimed nucleic acids.

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

As SEQ ID NO:2 is assigned to an amino acid sequence that is 419 amino acids in length, and the claims require at least 90% amino acid identity, a skilled artisan would instantly recognize that the claimed invention is directed to nucleic acids encoding proteins that share at least 378 amino acids with SEQ ID NO:2. The limitation that the polypeptide also possesses one or more biological activities of a full length IKK-γ polypeptide further informs the skilled artisan that only a subset of the nucleic acids encoding proteins that share at least 378 amino acids with SEQ ID NO:2 are encompassed by the claims. The claimed nucleic acids are easily identified through use of the methods disclosed in the Specification, and are readily conceivable based on common knowledge of conservative amino acid changes. For instance, one skilled in the art recognizes that a nucleic acid encoding a protein having "one or more modifications such as amino acid additions, deletions or substitutions relative to the amino acid sequence of SEQ ID NO:2 " (Specification, at page 20, lines 9-11), which do not disrupt the coiled-coil and/or leucine zipper α-helical regions of IKKγ (Figures 2b and 2c), retain homotypic (Claim 34) and heterotypic (Claims 31-33) binding activity of the wild type protein (Specification, at page 19, lines 7-11).

Applicants point the Examiner to the Revised Interim Written Description Guidelines Training Materials of the Office for assessing whether the claims meet the written description requirement. In particular, Applicants direct the Examiner's attention to Example 9, which teaches that the disclosure of a single nucleic acid, which specifically hybridizes to a given sequence under highly stringent conditions and encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity, meets the written description requirement. Similarly, Applicants disclosure of SEQ ID NO:1 (a nucleic acid encoding a full length IKK-γ protein), provides support for the genus of Claim 11 comprising explicit structural (high percent identity in place of stringent hybridization language), as well as functional limitations.

Additionally, in lodging the written description rejection of Claims 11 and 31-34, the Examiner has turned to the MPEP and cited specific case law:

> the patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays . . .

> there was no disclosure of which peptides, polynucleotides, and small molecules selectively inhibit PGHS-2 (Office Action, pages 2-5).[2]

In contrast to the case law cited by the Examiner, Applicants have disclosed at least one nucleic acid encompassed by the claims in question, as well as various methods for assessing IKK-γ function. Additionally, Applicants have identified numerous U.S. patents issued since 1976 containing claims to nucleic acids or proteins described by sequence similarity to a given SEQ ID NO and a function of the wild type molecule (*See, e.g.,* U.S. Patent No. 6,590,077). Taken together, the teachings and precedents set by the Office, indicate that the claims as written meet the written description requirement.

Moreover, regarding Claim 30, the Examiner has withdrawn the prior indication of allowability and lodged a new matter rejection. In particular, the Examiner states that:

> [n]o support for antisense polynucleotides of less than nine contiguous nucleotides can be found in the specification. Additionally, no support can be found in the specification for "human origin" antisense polynucleotides. The specification does not describe the characteristics of an antisense polynucleotide of human origin that would distinguish it from an antisense polynucleotide not of human origin (Office Action, pages 5 and 6).

Although Applicants respectfully disagree with the Examiner, Applicants have amended Claim 30, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claim 30 to recite an "isolated antisense polynucleotide, comprising a nucleotide sequence complementary to nucleotides 149 to 1408 SEQ ID NO:1." Support for this amendment is found for instance in Claim 14, as well as the Specification as filed which teaches that an

> antisense nucleic acid molecule of the invention can contain a sequence complementary to the entire coding sequence [e.g., nucleotides 149 to 1408] of SEQ ID NO:1 (Specification, at page 34, lines 3-9).

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2 Citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

Applicants believe that the claim amendments obviate the written description and new matter rejections, and accordingly request that these rejections be withdrawn.

2) The Claims Are Novel

The Examiner has rejected Claim 30 under 35 U.S.C. § 102(a) as allegedly anticipated by Hillier *et al.*, GENBANK Accession No. AA402683 (Hillier). The Examiner states that the:

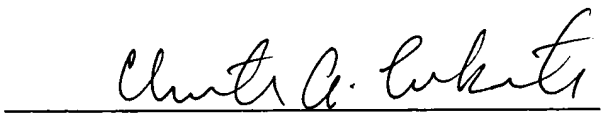
> database search of SEQ ID NO:1 discloses a 572 bp human nucleic acid containing a region complementary to more than 500 contiguous nucleotides of SEQ ID NO:1[, which] was disclosed to the public by Hillier et al. on November 9, 1997 (Office Action, pages 6 and 7).

Applicants respectfully disagree that the invention is anticipated by Hillier. Nonetheless, as described above in Section 1, Applicants have amended Claim 30 to recite an " isolated antisense polynucleotide, comprising a nucleotide sequence complementary to nucleotides 149 to 1408 SEQ ID NO:1." As the claimed antisense polynucleotide comprises nucleotide sequence not disclosed by Hillier, the claimed antisense polynucleotide is novel. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the amendments and arguments set forth above traverse the Examiner's rejections and, therefore request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

Dated: October 4, 2005



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